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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

LEAVITT, MARIA GOMEZ

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/528,748	Applicant(s) JUNGHANS ET AL.	
	Examiner MARIA LEAVITT	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05-08-2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-13, 15-20 and 22-38 is/are pending in the application.
- 4a) Of the above claim(s) 13, 15-20, 25-28, 31-34, 37 and 38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-12, 22, 29, 35 and 36 is/are rejected.
- 7) ☒ Claim(s) 23, 24 and 30 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05-08-2009 has been entered.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Claims 8-13, 15-20, 22-38 are pending. Claims 2, 3, 6, 7 and 21 have been cancelled; claims 8, 9, 11 and 12 have been amended and claims 22-38 have been added by Applicants' amendment filed on 05-08-2009. Claims 13, 15-20 were previously withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim by Applicants' amendment filed on 11-25-2008.
4. New claim 22 is drawn to a DNA expression construct comprising the nucleotide sequences of SEQ ID NOS: 5, 7 and 8. Applicants elected to prosecute with traverse in the response filed on 04-11-2008 the invention comprising the nucleotide sequence of SEQ ID NO: 5 encoding a mutated codon optimized *gag* gene. In reviewing and considering the requirements for election restriction mailed on 03-11-2008, the examiner is withdrawing the restriction requirements among nucleic acid molecules of SEQ ID NO: 5 (e.g., mutated *gag* gene), SEQ ID NO: 7 (e.g., the mutated *env* gene gp85) and

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SEQ ID NO: 8 (e.g., mutated env gene gp70). Accordingly, the sequences of SEQ ID NOS: 5, 7 and 8 are examined as species. To the extent that claims 25-28, 31-34 and 37-38 are drawn to non-elected species, claims 25-28, 31-34 and 37-38 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. The examiner notes that the nucleotide sequence comprising the sequence of SEQ ID NO: 5 is free of prior art. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

5. Accordingly, claims 8-12, 22-24, 29, 30, 35 and 36 are currently under examination to which the following grounds of rejection are applicable.

Withdrawn Rejections in response to Applicants' arguments or amendments

Specification objection

In view of Applicants' amendment of the Specification at paragraph [0125], to state that the Kazusa Institute is responsible for maintaining the data base related to codon usage table for cats and is accessible to anyone in the field and is therefore considered non-essential material, objection to the specification as related to paragraph [0125], has been withdrawn.

Claim Rejections - 35 USC § 102

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In view of Applicants' cancellation of claim 21, rejection of **claim 21** and dependent **claims 6 and 12** under 35 USC. 102(b) as being anticipated by Khan et al., (U.S. Patent No. 6,248,582; Date of Patent June 19, 2001) is rendered moot.

In view of the withdrawn rejection, applicants' arguments are rendered moot.

Claim Rejections - 35 USC § 103

In view of Applicants' cancellation of claim 21, rejection of **claim 21** and dependent **claims 7, 8, 9-11** under 35 U.S.C. 103(a) as being unpatentable over Khan et al., US 6,248,582 (Date of Patent June 19, 2001) in view of Schirmbeck et al., (J Mol Med. 2001; pp. 343-50) is rendered moot.

In view of the withdrawn rejection, applicants' arguments are rendered moot.

In view of Applicants' cancellation of claim 21, rejection of **claim 21** and dependent **claims 2 and 3** under 35 U.S.C. 103(a) as being unpatentable over Khan et al., US 6,248,582 (Date of Patent June 19, 2001) in view of Schirmbeck et al., (J Mol Med. 2001 ; pp. 343-50) as applied to claims 7-11 and 21 above and further in view of Shiver et al., (US Patent. 6,696,291 (Date of Patent Feb. 24, 2004), Laprevotte et al., (1984, J. Virol. , pp. 884-894 Genbank Accession No., K01803, FeLV gag cDNA) and Gardner-Arnstein feline leukemia oncovirus codon usage (www.kazusa.or.jp/codon, of record) is rendered moot.

In view of the withdrawn rejection, applicants' arguments are rendered moot.

Objections/Rejections maintained in response to Applicants' arguments or amendments

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Notice To Comply with Sequence Rules For Patent Applications Containing nucleotide Sequence And/Or Amino acid Sequence Disclosures

Applicants filing of a revised paper sequence listing and identification of the claimed peptide sequence comprising PKKKRKV as SEQ ID NO:41 is acknowledged. However, the reply filed on 05-08-2009 is not fully responsive to the prior Office Action because of the following omission(s) or matter(s):

a sequence listing in computer readable form including SEQ ID NO: 41 has not been filed, and

a statement that the information recorded in computer readable form is identical to the content of the paper sequence listing, as required by 37 CFR 1.821 (e) or 37 CFR 1.821 (f) or 37 CFR 1.821 (g) or 37 CFR 1.821 (b) or 37 CFR 1.821 (d).

Additionally, this application fails to comply with the requirements of 37 CFR 1.821 (d), which states:

(d) Where the description or claims of a patent application discuss a sequence that is set forth in the "Sequence Listing" in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO:" in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application.

The specification and claims disclose amino acid and nucleotides sequences which are described or named with improper identifiers, for example, at page 18, on lines 5, a sequence identifier for sequence ID NO:5 should be abbreviated as SEQ ID NO:5 and not Seq.ID5.

Claim Rejections - 35 USC § 102

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New claim 36 is interpreted as a product by process claim. SEQ ID NO:5 is a gag coding sequence, accordingly, claim 36 is broadly interpreted as comprising a genus of nucleotide sequences of SEQ ID NO: 5 generated by primers which selectively hybridize to sequence ID NO: 5. The specification does not provided a closed definition of “primers which selectively hybridize” but discloses in example 7 specific primers used to clone FeLVgag. Primers that hybridizes to the nucleotide sequence encoding SEQ IN NO:5, even under stringent conditions, requires only that two nucleic acids share between 25 and 50 nucleotides in common. (Kennell, *Progr Nucleic Acid Res. Mol. Biol.* 11: 259-301, 1971, at the paragraph bridging pages 260-261). To the extent that new claims 23 and 36 are drawn to nucleotides that read on fragments or domains of SEQ ID NO:5 with any percentage of homology, the following rejection is maintained over claims 23 and 36.

Claims 23 and 36 are newly rejected under 35 USC. 102(b) as being anticipated by Paoletti E (WO9215672, Date of publication 17-Sep-1992; see Result 5, SCORE Search Results Details for Application 10528748 and Search Result 20080609_130757_us-10-528-748-5.rng) as evidenced by Kennell (*Progr Nucleic Acid Res. Mol. Biol.* 11: 259-301, 1971, at the paragraph bridging pages 260-261)..

Paoletti E et al., teaches a 3674bp nucleotide sequence of Fig. 27 which encodes the feline leukemia virus (FeLV-A) gag gene, said nucleotide sequence having a nucleotide homology of 52.7% homology to the nucleotide sequence of instantly disclosed SEQ ID NO: 5 (see Result 5, SCORE Search Results Details). In addition, Paoletti E teaches constructs comprising the vaccinia virus H6 promoter and the FeLV-A pol gene. Furthermore, Paoletti E. et al., discloses that the construct is use as a vaccine in cats (p. 82, last paragraphs). Antibodies

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elicited against the product of the construct comprising a promoter and nucleotide encoding the feline leukemia virus (FeLV-A) *gag* gene clearly indicate that the promoter is operably linked to the FeLV-A *gag* gene sequence (p. 98, Table12).

Thus by teaching all the claims limitations, Paoletti et al., anticipate the instant invention as related to isolated nucleotide fragments amplified by primers that selectively hybridize to SEQ ID NO:5 as evidenced by Kennell.

New grounds of objection/rejection

Numbering of Claims

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

For the purpose of a compact prosecution misnumbered claims 38 and 39 have been renumbered as 37 and 38. However, full compliance with the numbering of claims is required in response to this Office Action. A complete response to this office action should include both compliance with the numbering of claims, and a response to the rejections set forth below. Failure to comply with **both** these requirements in the time period set forth in this office action will be held non-responsive.

Claim Objection

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Claims 8-12 and 22-24, 29, 30 35 and 36 are directed to a polynucleotide “shown in” SEQ ID NO: 5. It is unclear whether the phrase “shown in” should be interpreted narrowly to encompass only materials that have a structure identical to the SEQ ID NO:5 or if the phrase should be interpreted broadly to encompass materials which have a structure “similar” to the SEQ ID NO:5. Amending the claims to recite “as set forth” would be remedial.

Claim 36 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Specifically, SEQ ID NO: 5 is a gag coding sequence. Claim 36 is a product by process PCR of such sequences from SEQ ID NO: 5. Accordingly, any PCR fragments from any gag sequence portion of SEQ ID NO: 5 would anticipate claim 36, but not the parent claim as claim 23 requires the entire sequence i.e., prior art could anticipate the dependent claim but not the parent.

Additionally, Claim 24 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Specifically, SEQ ID NO: 5 has a sequence encoding a gag related structural protein. Claim 24 is of the same scope of parent claim 23 and does not further limit the breadth of claim 23.

Claim Rejections - 35 USC § 112- Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 8-12, 22, 35 and 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 22 recites, wherein said mutated nucleotide sequence encodes at least one of a structure protein “gag” and a membrane protein “env” from the group consisting of SEQ ID NOS: 5, 7 and 8. The phrase “at least one of a structure protein “gag” and a membrane protein “env” can be broadly but reasonably interpreted as encoding both a structure protein “gag” and a membrane protein “env”. However, each of SEQ ID NOS 5, 7 and 8 encodes separately a mutated "gag" gene, a mutated "env" gene (gp85) or a mutated "env" gene (gp70), respectively. Thus it is unclear how the mutated nucleotide sequence encodes both a “gag” and “env” proteins from nucleotide sequences as set forth in at least one of SEQ ID NOS 5, 7 or 8. As such, the metes and bounds of the claim cannot be determined.

Moreover, claim 36 is indefinite in the reciting of “the gag coding sequence” at lines 1-2, and “the same sequence” at lines 2-3. There is no antecedent basis for any of “the gag coding sequence” and “the same sequence” in the claim or claim 23 from which it depends. As such, the metes and bounds of the claim cannot be determined.

Claims 8-12 and 35 are rejected insofar as they depend on claim 22

Conclusion

Claims 8-12 and 22, 29, 30, 35 and 36 are rejected.

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Claims 23, 24 and 30 are objected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria Leavitt whose telephone number is 571-272-1085. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

/Maria Leavitt/

Maria Leavitt, PhD
Examiner, Art Unit 1633

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